

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

**Public Board Meeting held on 15 March 2017 in Durham Town Hall, Market
Place, Durham, DH1 3NJ**

These notes are a summary record of the main points discussed at the meeting and the decisions made. They are not intended to provide a verbatim record of the Board's discussion. The agenda and the full documents considered are available in accordance with the NICE Publication Scheme.

Present

Professor David Haslam	Chair
Professor Sheena Asthana	Non-Executive Director
Dr Rosie Benneyworth	Non-Executive Director
Professor Angela Coulter	Non-Executive Director
Professor Tim Irish	Non-Executive Director
Dr Rima Makarem	Non-Executive Director
Andy McKeon	Non-Executive Director

Executive Directors

Sir Andrew Dillon	Chief Executive
Professor Gillian Leng	Health and Social Care Director and Deputy Chief Executive
Ben Bennett	Business Planning and Resources Director
Professor Carole Longson	Centre for Health Technology Evaluation Director

Directors in attendance

Professor Mark Baker	Centre for Guidelines Director
Alexia Tonnel	Evidence Resources Director

In attendance

David Coombs	Associate Director – Corporate Office (minutes)
Moya Alcock	Associate Director – Corporate Communications and Deputy Communications Director

17/018 APOLOGIES FOR ABSENCE

1. Apologies were received from Professor Martin Cowie, Elaine Inglesby-Burke, Tom Wright, and Jane Gizbert.

17/019 CONFLICTS OF INTEREST

2. Tim Irish highlighted that he has recently taken up the following roles:
 - Board Member, Pistoia Alliance Advisory Board

- Supervisory Board Member, Fiagon AG
 - Professor of Practice, Kings College London.
3. David Haslam confirmed these had been entered into the register of interests, and the appointments did not represent a conflict of interest in relation to the matters to be discussed at this meeting.

17/020 MINUTES OF THE LAST MEETING

4. The minutes of the public Board meeting held on 18 January 2017 were agreed as a correct record.

17/021 MATTERS ARISING

5. The Board reviewed the actions arising from the Board meeting held on 18 January 2017.
6. Moya Alcock confirmed that the report on the regional stakeholder engagement events had been published on NICE's website and circulated to those who attended.
7. It was noted that the Remuneration Committee does not have a role in the clinical excellence awards, and therefore no further amendments are required to the committee's terms of reference. In addition, the vacancies for the non-executive director positions on the Clinical Excellence Awards Committee have been filled.
8. The actions relating to publicising the respective roles of NICE and Public Health England (PHE), and taking forward NICE's support for the life sciences industry are in progress.

17/022 CHIEF EXECUTIVE'S REPORT

9. Andrew Dillon presented his report, describing the main programme activities to the end of February 2017 and the financial position to the end of January. He outlined NICE's contribution to the development of the Government's Life Sciences Strategy, including through membership of the Senior Officials Leadership Group.
10. Andrew noted that NICE has secured resources to test the feasibility of a process to assess the potential environmental impact of guidance recommendations. Following this feasibility study, consideration will be given to whether this should be developed further so that NICE evaluations take account of environmental as well as cost impact.
11. The Board received the report.

17/023 FINANCE AND WORKFORCE REPORT

12. Ben Bennett presented the report which outlined the financial position as at 31 January 2017 and provided an update on the workforce strategy. The year-end forecast out-turn remains consistent with that previously reported to the Board – a £3.4m underspend against the revenue resource limit. Formal confirmation of the revenue resource limit for 2017-18 has now been received. This is in line with the assumptions in the draft business plan, presented later in the agenda. Ben highlighted the preparations to ensure compliance with new regulations regarding the tax arrangements of ‘off payroll’ contractors in the public sector. He noted the potential impact of the new regulations on the Evidence Resources directorate.
13. The Board received the report.

17/024 BUSINESS PLAN 2017-18

14. Andrew Dillon presented the 2017-18 business plan for the Board’s review and approval. He highlighted the proposed business objectives and accompanying actions, progress against which will be included in the bi-monthly Chief Executive’s report.
15. Sheena Asthana referred to paragraphs 10 and 11 in the business plan and asked whether alternative language could be used to more effectively explain NICE’s support for decommissioning to patients and clinicians. The Board discussed the challenge of adopting terminology that articulates these initiatives to the diverse audience of commissioners, patients, clinicians, and other parties in the health and care system. Andrew Dillon stated that he would be willing to consider alternative terminology.
16. The Board approved the business plan and delegated approval of any final amendments, including in relation to the point raised above, to the Chief Executive.

17/025 REVISIONS TO STANDING ORDERS, STANDING FINANCIAL INSTRUCTIONS, AND RESERVATION OF POWERS TO THE BOARD

17. Ben Bennett presented the summary of the proposed changes to the governance documents following an annual review. He asked the Board to consider the position of the recently appointed deputies to the Senior Management Team members when attending Board meetings.
18. Andy McKeon referred to the proposed amendment to the Reservation of Powers to the Board regarding the approval of policies. He asked which management policies will require Board approval. Ben Bennett agreed to report back to the Board on this matter.

ACTION: Ben Bennett

19. Rima Makarem, Chair of the Audit and Risk Committee (ARC), asked about the respective roles of the Board and ARC in relation to the annual report and accounts. Ben Bennett stated that due to the timescales for finalising the annual report and accounts, and laying these before Parliament, the Board has delegated the authority to approve the annual report and accounts to the ARC. The approved annual report and accounts are then formally presented to the Board for information at the annual general meeting. Following a question from Rima Makarem on whether the Board required a greater role in reviewing the annual report and accounts, it was agreed that the draft annual report and accounts will be circulated to the Board for comment prior to review by the ARC at its June meeting. In addition, all Board members will be invited to attend the ARC meeting in June that reviews and approves the annual report and accounts.

ACTION: Ben Bennett

20. The Board discussed the role of the deputy directors and agreed the deputies would only have voting rights and count towards the quorum of a Board meeting when formally appointed to assume the relevant director's responsibilities in the event of an absence over 4 weeks. This will be reflected in the Standing Orders.
21. Subject to the above amendment, the Board approved the amendments to the Standing Orders, Standing Financial Instructions, and Reservation of Powers and Scheme of Delegation to the Board.

ACTION: David Coombs

17/026 UPTAKE AND IMPACT REPORT

22. Gill Leng presented the six-monthly uptake and impact report, and asked the Board to consider the format for future reports. She thanked Paul Chrisp and colleagues in the Health and Social Care directorate for their work in compiling the report.
23. The Board discussed the report, noting and welcoming the extent of information provided. A number of comments were made about the indicators in the report, with a suggestion to give greater focus to those in which there has been a significant change in uptake, and which most directly relate to the impact of NICE guidance. A rationalisation of indicators for the field team was also suggested, with these aligned to the priorities for the team's engagement activities.
24. In terms of future reporting, it was agreed that each public Board meeting should receive an update on the uptake and impact of NICE's work, focused on a specific topic. Further information will be available on the NICE website and regularly updated. It was also agreed that consideration is given to a small

number of indicators that could be used to measure NICE's impact, progress against which would also be regularly reported to the Board.

ACTION: Gill Leng

25. A member of the public referred to how NICE guidance refers to informed consent and suggested how uptake of this guidance could be measured and evaluated.
26. A member of the public asked about NICE's impact on the emerging Sustainability and Transformation Plans (STP). Gill Leng noted that it is not yet possible to evaluate the impact of the engagement given the relatively early stage in the development of STPs. However, NICE will continue to review its engagement with the STPs to ensure this is as effective as possible.

17/027 APPROPRIATE DISINVESTMENT AND INVESTMENT: SUPPORT FROM NICE

27. Gill Leng presented the progress update on NICE's redesigned support for delivering appropriate care and disinvestment. Referring to the comments earlier in the meeting, Gill acknowledged that it is challenging to find a single suitable term to refer to this work. The language used will therefore vary according to the context and the target audience.
28. The Board discussed the report, raising a number of comments and observations. The importance of supporting primary care, in addition to secondary care, was highlighted, as was the importance of working with national health and social care partners to influence practice. The proposal to utilise the upcoming NICE conference to promote the narrative around NICE's support for appropriate investment and disinvestment was welcomed. The Board discussed this narrative, emphasising the importance of tailoring this for different audiences: patients, clinicians, commissioners, and finance professionals. It was suggested that framing this around quality and safety would ensure greater traction with patients and clinicians.
29. The Board noted the report and agreed that further updates would be provided through the Health and Social Care directorate progress reports, as appropriate.

ACTION: Gill Leng

17/028 A REPLACEMENT FOR THE HEALTH SERVICE CIRCULAR 2003/011

30. Carole Longson presented the proposed replacement for the Health Service Circular 2003/011 (The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation), which was approved by the Board.

17/029 CONSULTATION ON CHANGES TO THE TECHNOLOGY APPRAISAL AND HIGHLY SPECIALISED TECHNOLOGIES PROGRAMMES

31. Carole Longson introduced the item on the outcome of the NICE and NHS England consultation on changes to the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programmes. She noted that aspects of the proposals have been revised in response to the consultation feedback. Andrew Dillon highlighted the extent of concerns raised by the patient and industry groups, but stated that the proposals seek to guide NICE's recommendations in the context of the financial constraints for the health and care system.
32. The Board reviewed the consultation feedback and the proposed changes to the programmes.

Budget impact

33. Carole Longson outlined the proposal to introduce a budget impact test of £20m. Should a new technology exceed this threshold in any of the first three years of its introduction to the NHS, a commercial negotiation would be triggered. Should this negotiation fail to conclude or fully address budget impact issues, NHS England would be able to apply to NICE to vary the funding requirement to phase introduction of the technology over a longer period to help manage its budget impact.
34. Following the consultation, the overall proposition remains unchanged. However, the process for NICE considering a request to vary the funding requirement has been explicitly articulated, along with the information NHS England will need to provide when submitting any such request. It has also been further clarified that discussions on budget impact are separate to the NICE committee's evaluation of cost effectiveness. The terminology has also been revised from 'budget impact threshold' to 'budget impact test', to clarify that it is not a maximum level of expenditure.
35. The Board considered the proposals, in the context of the consultation feedback received. It was noted that NICE will use the company submission as the starting point for assessing the budget impact of a new technology. The Board also highlighted the importance of clearly explaining to patients, clinicians and other stakeholders, the arrangements for accessing the technology when NICE has agreed to vary the funding requirement.
36. Andy McKeon suggested a need to simplify the process for companies engaging in commercial discussions around the pricing of new technologies. He stated that the new documentation should more clearly indicate that a decision to vary the funding direction is subject to appeal, and that the budget impact assessment is separate to the committee's consideration of cost effectiveness. He also suggested that NICE should ensure the submission from NHS England to request a variation in the funding direction, should reflect the information NICE's Guidance Executive will receive when considering the request.

37. The Board approved the proposals for the budget impact test and for managing requests for variations to the funding requirement, as laid out in the report. The Board approved the accompanying process and methods statements, and agreed to put in place the arrangements for managing the budget impact test for topics for which a first evidence submission is received after 1 April 2017.
38. The Board noted the proposal to review the application of the budget impact test after three years.

Fast-track appraisals (FTA)

39. Carole Longson outlined the proposal to introduce a process for providing faster access to treatments that are highly cost effective. She stated that in response to feedback, the budget impact test will not be used as an entry criterion for the FTA as this could filter out products that are extremely cost effective but could have a high budget impact.
40. The Board considered the proposals in the context of the consultation feedback received. In response to a question from the Board, it was clarified that whilst the budget impact test has been removed as a criterion for entry to the FTA, NHS England will be able to request variation of the funding requirement for technologies assessed through the FTA which have a budget impact above £20m in any one of the first three years of introduction in the NHS.
41. The Board approved the introduction of fast track appraisals as outlined in the report, together with the accompanying methods statement. It was agreed that the proposals will take effect for topics with a first evidence submission from 1 April 2017.
42. The Board noted that a proposal to extend the fast track concept to a wider group of topics will be brought to the Board in due course, given the support for the concept of the FTA in the consultation.

Highly specialised technologies (HST) programme

43. Carole Longson outlined the proposal to introduce quality adjusted life years (QALY) as a measure of value in the HST programme, and on the application of a limit of £100k per QALY below which the funding requirement would apply. She stated that in response to the consultation feedback, a revised approach is proposed. This will involve the introduction of a QALY weighting, which will progressively advantage treatments that offer greater QALY gains.
44. Andrew Dillon highlighted that in response to consultation feedback, the proposed opportunity for topics to be considered by NHS England's Clinical Priorities Advisory Group after evaluation by NICE's Highly Specialised Technologies Evaluation Committee has been withdrawn.

45. Carole Longson stated that the process and methods statement for the programme will be comprehensively reviewed in light of these changes, and brought to the Board.
46. The Board discussed the proposals in the context of the consultation feedback received. The importance of clearly explaining the changes and their rationale was highlighted, in particular to patient groups.
47. The Board approved the proposals as set out in the report, to take effect for topics that are initiated after 1 April 2017. NICE and NHS England will review the revised arrangements, and make amendments if necessary, after three years.

17/030 DIRECTOR'S REPORT FOR CONSIDERATION

48. Carole Longson presented the update from the Centre for Health Technology Evaluation. She drew the Board's attention to key items of note in the report, including the discussions with NHS England and other key stakeholders regarding proposals for NICE to develop a national, systematic framework for tracking innovative non-drug technologies in development (MedTechScan). She also highlighted the Centre's involvement in European initiatives on the use of observational and real world data.
49. The Board received the report and thanked Carole Longson for the work of the Centre.

17/031 – 17/034 DIRECTORS' REPORTS FOR INFORMATION

50. The Board received the Directors' Reports.

17/035 AUDIT AND RISK COMMITTEE MINUTES

51. The Board received the unconfirmed minutes of the Audit and Risk Committee held on 25 January 2017.
52. Rima Makarem, Chair of the Audit and Risk Committee, stated that following recent turnover in membership, the Committee are reviewing its approach to a number of matters. In particular, the Committee considered in depth NICE's approach to risk management and proposals for a revised process will be brought to the Board shortly.

17/036 ANY OTHER BUSINESS

53. None.

NEXT MEETING

54. The next public meeting of the Board will be held at 1.30pm on 17 May 2017 in Chester Town Hall, 33 Northgate Street, Chester, CH1 2HQ.